



English

Operating Instructions

ATMOS Record 55 DDS



444.0910.B
444.0930.B
444.0940.B
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1.1 Notes on operating instructions

- This document is valid for following basic units:

- ATMOS Record 55 DDS REF 444.0910.0
- ATMOS Record 55 DDS Lipo REF 444.0920.0

as well as for variants, consisting of above mentioned basic units in connection with following options:

- APEC canister set 2 x 3 l REF 444.0901.0
- APEC canister set 2 x 5 l REF 444.0902.0
- Foot regulator set REF 443.0770.0
- Foot switch REF 443.0755.0

- These operating instructions contain important information on how to operate the Record 55 DDS safely, correctly and effectively. The operating instructions are intended for new operating personnel and also should be continued to be used as a reference manual. Reading and understanding the operating instructions will assist the user in avoiding risks, reducing repair costs, lowering down-time, increasing reliability and extending the service-life of the equipment.

The operating instructions must always be kept available and near the equipment.

Prior to first use, please read the chapter 2.0 "For your safety", to be prepared for any possible dangerous situations.

The basic principles are:

Judicious and careful work provides the best protection against accidents!

Operational safety and readiness for use depend not only on your capabilities, but also on **care and maintenance** given to the ATMOS Record 55 DDS. Regular cleaning and service work are a must. Major maintenance and repair work should be carried out only by expert personnel authorised by ATMOS. For repairs, only use ATMOS spare parts to preserve the equipment warranty and ensure operational safety, readiness for work and to maintain the value of the equipment.

- The product ATMOS Record 55 DDS bears CE Marking CE-0124 according to the EEC guideline of the council for medical products 93/42/EEC and meets the basic requirements of this guideline.
- The product ATMOS Record 55 DDS complies with all applicable requirements of the directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").
- The declaration of conformity can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN 13485.
- Reprints and text extracts are allowed only with written permission from ATMOS.

Abbreviations / symbols in these operating instructions:

- Indicating a list
 - Subdivision of a list/activity

The recommended sequence must be followed in each case!

Indicating particularly important advice!

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1.2 Intended use

Name: ATMOS® Record 55 DDS

Main functions:

Suction of secretions, rinsing fluids and temporarily collection of body fluids.

Med. indications/ application:

For surgeries e.g. suction of wound cavities, abscesses etc.

For endoscopy e.g. suction of secretions and rinsing fluids.

For spontaneous suction of body fluids.

For subcutaneous liposuction.

Specification of the main function:

Drainage and temporarily collection of body fluids. By means of an electrical suction pump, a negative pressure will be created. The integrated secretion canister allows a temporarily collection of the derived body fluids.

Application organ:

Natural orifices as well as openings which are created by means of a surgery (whole body; human and animal).

Application time: Short-term use on the patient (< 30 days).

Application site: The application site is the clinical, outpatient, practices as well as the veterinary medicine area.

The application of the device may only be performed by medical trained and introduced staff.

Contraindications:

No application in low-vacuum range e.g. thoracic and wound drainage.

No application outside of the medical sector.

No suction of flammable, corrosive and explosive substances.

No application for the vacuum extraction.

The product is: active not active

Sterility: Not necessary

Single use product / reprocessing:

The device and the accessories are partially reusable. For information on reprocessing, cleaning and disinfection see user manual.

1.3 Function

- The ATMOS Record 55 DDS is a line-power operated surgical suction unit, centering around a silent, maintenance-free diaphragm pump which generates a vacuum inside the secretion canister, allowing secretions to be withdrawn and collected. Using a vacuum regulator and the vacuum-gauge, the target vacuum and thus the air-flow rate can be precisely adjusted.
- Several secretion canisters of different sizes are available for use with the system (section 8.0 Spare parts and accessories). A hydrophobic bacterial filter in the lid of the secretion canister is implemented to prevent secretions from entering the pump resp. bacteria the interior of the unit.
- All parts of the secretion canister system and the silicone hoses (with the exception of the bacterial filter) that come into contact with secretions may be autoclaved (134 °C, 3 bar, 5 min. 3x fractionated prevacuum).

1.4 Explanation of symbols



Attention, refer to operating instructions !



Fuse



Potential equalization



Type BF equipment



Alternating current

IPX1

Protection against penetration of
damaging humidity (drop water)



Foot switch



Class AP,
for use in explosion-hazardous areas

2.0 For your safety



- The design of the ATMOS Record 55 DDS fulfills the requirements of IEC 601/EN 60601 and of protection class I. The device must only be connected to a properly installed socket with non-fused earthed wire.
- Before putting the device into operation, visually check unit, secretion canister, power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately. Check also function of the unit.
- Dispose of the packaging material, observing the applicable waste-control regulations.
- Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are similar to those indicated on the device.
- The ATMOS Record 55 DDS may be used in **supervised operation** by qualified personnel only which has been authorised by ATMOS and which has been trained for operating the appliance (IEC 601-1/EN 60601-1).
- Never connect the unit to defective power sockets or extension cables.
- Prior to first use, remove the transport protection on the bottom side of the unit.
- After transport at cold temperatures, the unit must acclimatize prior to first use; leave it unoperated at room temperature for a period of up to 6 hours. If the unit is **not** acclimatized it **must not** be operated as the membranes of the pump might get damaged.
- The suction hose must never come into direct contact with the application site. A suction catheter, attachment or a medical aspiration set must always be connected to the hose.
- Disconnection of the device from the power line is only possible by pulling the mains plug! First remove the plug from the wall outlet. Then the power cord may be disconnected from the device. Never touch the plug or cord with wet hands.
- The ambient conditions specified in section 9.0 must be strictly observed.
- Set up the device so that the operator has a clear, unobstructed view of and easy access to the front panel. The device must be placed on a solid, level surface.
- The ATMOS Record 55 DDS may be operated only in rooms used for medical purposes, but not in areas (zones M and G) subject to **explosion hazards and in oxygen rich environments**. Explosion hazards may result from the use of combustible anaesthetic agents, skin cleansing agents or disinfectants.
- The foot switch is suited for operation in above mentioned areas.

2.0 For your safety



- Liquids must not be allowed to enter the device. Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.
- The ATMOS Record 55 DDS fully complies with the electromagnetic immunity requirements of standard **IEC 601-1-2 / EN 60601-1-2** "Electromagnetic compatibility - Medical Electrical Equipment".
- ATMOS is not liable for personal injury and damage to property if
 - no original ATMOS parts are being used,
 - the advice for use in these operating instructions is not being observed,
 - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorised by ATMOS.
- This operation manual corresponds with the construction of the unit and with the current status of safety-related standards at the time of printing. Proprietary rights are existing for all described circuits, processes, names, software programmes and units.
- The Record 55 may never be used without a bacterial filter! Using the device without a bacterial filter could endanger patients, user or third persons, respectively damage the device.
- Please note:
A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.
- This product is not re-sterilisable. Repeated reuse of components which are marked with a is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.

3.1 Figures



Fig. 1. ATMOS Record 55 DDS, Front View
(illustration with canister set 2 x 3 l DDS)
① Connection for foot switch (option)
or foot regulator (option)
② Foot switch (option)



Fig. 2. ATMOS Record 55 DDS Lipo, Front View
(illustration with canister set 2 x 5 l DDS)
① Connection for foot switch (option)
② Foot switch (option)
③ Tumescent infiltration pump
ATMOS 2001 TI
④ Foot regulator (option),
connection (w/o illustration) on the left
side of the ATMOS 2001 TI
⑤ Hook for suspending
the bag with infiltration solution or
the full secretion canister

3.0 Installation and start-up



Fig. 3. Operating Controls and Indicators

- ① ON/OFF switch
(ON = continuous operation)
(OFF = foot switch operation)
- ② Vacuum regulator
- ③ Vacuumgauge
- ④ DDS canister handle
- ⑤ DDS canister lid
- ⑥ DDS secretion canister



Fig. 4. ATMOS Record 55 DDS, Rear View

- ① Connection for potential equalisation
- ② Fuse
- ③ Power input



Fig. 5.

Vacuum connection: Direct-Docking-System

The vacuum connection between the pump and the secretion canister is created automatically as soon as the DDS canister is positioned correctly.

4.1 First-time operation

- ☞ Before putting the device into operation for the first time, do not fail to read section 2.0 "For your safety".
- ☞ Remove transport protection on the bottom side of the unit by loosening the two red marked Allen screws.
- ☞ The transport protection screws removed before starting the unit for the first time must be inserted again when the unit is transported.
- ☞ After transport at cold temperatures, the unit must acclimatize prior to first use; leave it unoperated at room temperature for a period of up to 6 hours. If the unit is **not** acclimatized it **must not** be operated as the membranes of the pump might get damaged.

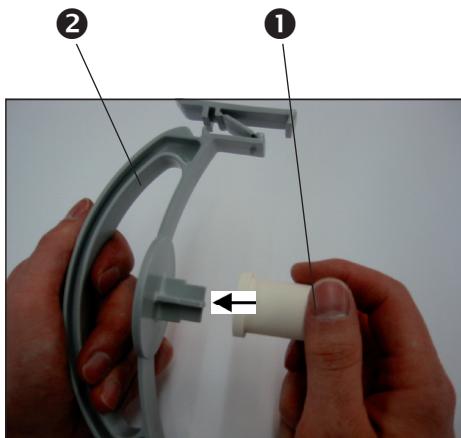


Fig. 6. ① Bacterial filter
② DDS canister handle

4.2 Insert / remove DDS bacterial filter/ oversuction stop

- The DDS bacterial filter/oversuction stop is disposable.
- ☞ Prior to each application, check whether the DDS bacterial filter/oversuction stop is dry and clean. Moist or contaminated filters must be replaced by new ones.
The filter has to be replaced when the vacuum value is above -0.3 bar while the vacuum regulator is adjusted to "max." and the suction hose is in open condition.
- Fix the bacterial filter (1, fig. 6) to the DDS canister lid (2, fig. 6) auf.
- ☞ Replace the DDS bacterial filter at least once a day. Use only original ATMOS bacterial filters!
Never operate the unit without the DDS bacterial filter/ oversuction stop as otherwise the warranty will expire!
- ☞ Use gloves after having operated the unit!



Fig. 7. DDS canister lid
① DDS splash protection

4.3 Using the DDS splash protector

- Add the DDS splash protection (1, fig. 7) to the connection on the DDS canister lid.

4.0 Operation



Fig. 8.



Fig. 9.



Fig. 10.

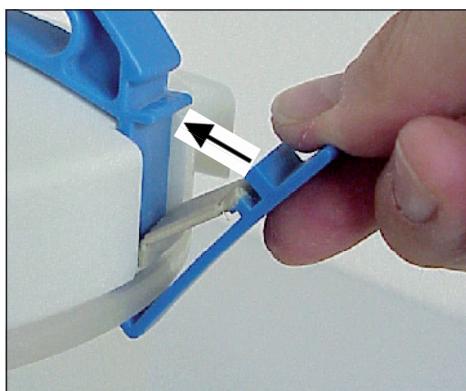


Fig. 11.

4.4 Attach / remove DDS secretion canister lid

- With the DDS secretion canister on a firm surface, position the lid horizontally on top (the lid may not be twisted!)
- Press down lightly onto the secretion canister using both hands until limit is reached.

- To open the DDS secretion canister, hold the canister firmly by the reinforcing clips of the securing device and then pull the DDS secretion canister lid up and off by gripping the filter hole.

4.5 Attach DDS secretion canister handle

- Insert the DDS secretion canister handle into the grooves of the lid with the snap-in hooks open.

4.6 Close / open DDS secretion canister handle

- To close, secure the snap-in hooks under the edge of the secretion canister, and then press the clips downwards until they lock into place.
- To open, pull the clips upwards to release the snap-in hooks and remove from under the edge of the secretion canister.



Fig. 12.



Fig. 12a.



Fig. 13.

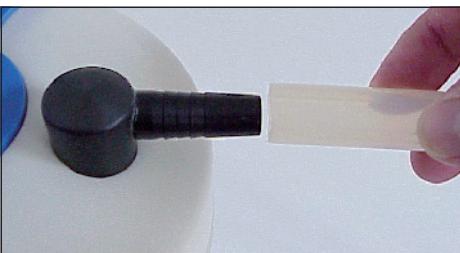


Fig. 14.

4.7 Secure DDS secretion canister

- For removal, lift the DDS secretion canister vertically upwards; for insert it again, allow it to slide vertically downwards into the securing device.

4.8 DDS hose holder

- In the case that you would like to use the hose holder REF 340.0066.0 please mount it between the canister lid and the hose adapter as described in figure 12a.

4.9 Insert DDS hose adapter

- Press the required DDS hose adapter with 6 mm or 10 mm diameter into the "Patient" hole of the DDS secretion canister lid twisting slightly to ensure a tight fit.
- Twist slightly in the same manner when removing.

4.10 Connect hose

4.11 Attaching the tumescence infiltration pump ATMOS S 2001 TI

- See assembly instructions.
- Assembly instructions are enclosed to the support for the tumescence infiltration pump.

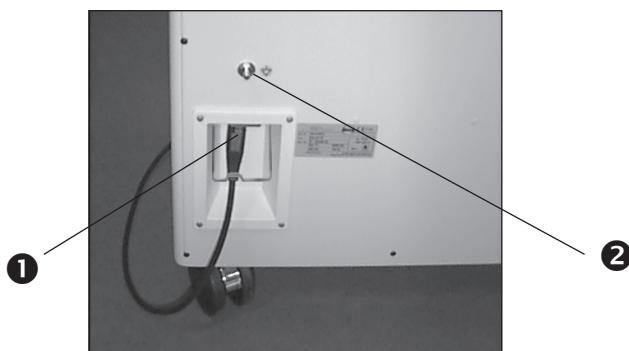


Fig. 15. ① Power input
② Potential equalisation

4.12 Checking the supply voltage

- Check that the power ratings marked on the device are identical with those of your local power line. Then connect the ATMOS Record 55 DDS to the power line (①, fig. 15).

For surgical use, we recommend to connect pin (②, fig. 15) of the ATMOS Record 55 DDS to the room's potential equalisation system. The ATMOS Record 55 DDS is then ready for operation.

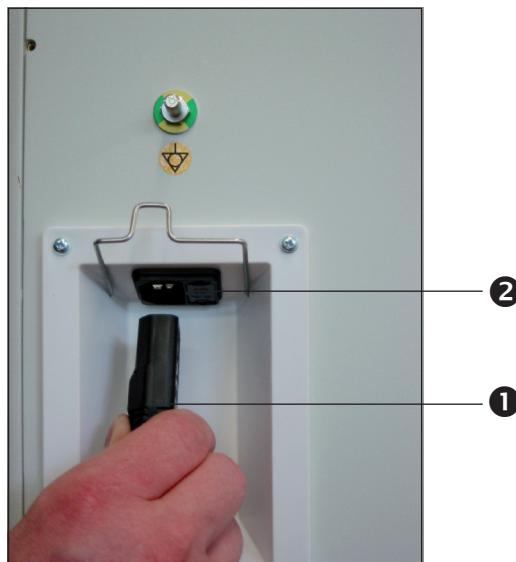


Fig. 16. ① Mains cable
② Connection for plug of non-heating appliance

4.13 Connecting the mains cable

- Insert the mains cable (①, fig. 16) in the socket for non-heating appliances (②, fig. 16).
- Secure the mains cable (①, fig. 17) with the safety clamp (②, fig. 17).

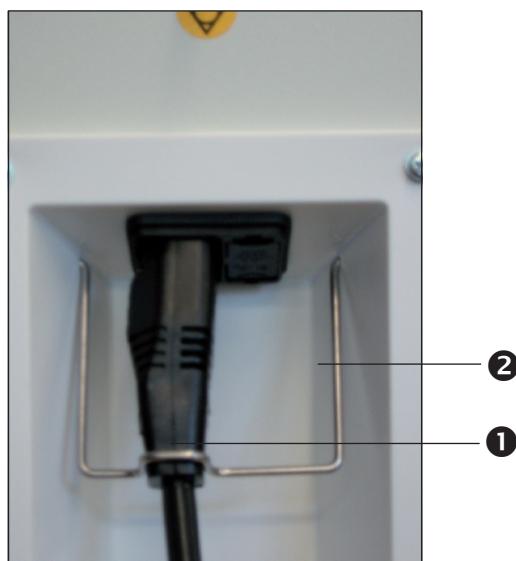


Fig. 17. ① Mains cable
② Safety clamp



Fig. 18.



Fig. 19a.



Fig. 19b.

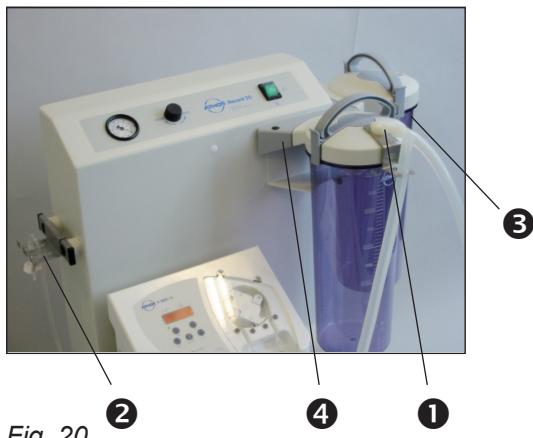


Fig. 20.

4.14 Suction

- Use appropriate suction catheters, suction tips or suction instruments.
- ⚠ Prior to starting suction, containers must be checked for cracks. Damaged containers may not be used.
- ⚠ Ensure that the suction hose and suction instruments as well as the entire secretion canister have been sterilized before each patient. Keep an eye on the level of liquid in the secretion canister during suction.
- The hydrophobic bacterial filter safely prevents liquid from getting into the pump. Nevertheless the secretion canister should be replaced when 2/3 full.

4.14.1 DDS changeover docking station (only with ATMOS Record 55 DDS)



Max load on station: 15 kg!
Damage on device at higher weight!

- The DDS changeover docking station for 2 secretion canisters with changeover switch and direct docking may be used on the ATMOS Record 55 DDS.
- The changeover lever (1, fig. 18) serves to switch the vacuum to the secretion canister towards which the lever points.
- To remove or insert a secretion canister, switch the changeover lever towards the secretion canister that is not being replaced.

4.14.2 Changing canisters with the ATMOS Record 55 DDS

- The secretion canisters are inserted into the DDS changeover docking station vertically from above (fig. 19).

4.14.3 Changing canisters with the ATMOS Record 55 DDS Lipo

- Interrupt the suction application and switch off the pump.
- Remove nipple and hose (1, fig. 20) from the full canister. Lift the full canister upwards from the support and replace it by an empty canister.
- Insert the second canister (3, fig. 20) vertically from above in the support on front (4, fig. 20). Then add nipple and hose to the canister lid and continue with the suction procedure.
- Dispose of the contents of the full secretion canister, observing the applicable waste control regulations.



Fig. 21.

4.15 Options

4.15.1 Foot switch, Art.No. 443.0755.0, with ATMOS Record 55 DDS and ATMOS Record 55 DDS Lipo

- Pneumatically explosion-proof foot switch (fig. 21) for turning the pump on and off.
 - Connect the foot switch (1, fig. 1, page 8).
 - Set the main switch to foot switch operation (OFF).
 - As soon as the foot switch is operated, the pump starts.
 - When the foot switch is operated again, the pump turns off again.
 - If the main switch is set to continuous operation (ON), the foot switch produces **no effect**.

4.15.2 Foot regulator set, Art.No. 443.0770.0, with the ATMOS Record 55 DDS

- Foot regulator for controlling the vacuum.
 - Connect the foot regulator (1, fig. 1, page 8).
 - To increase the vacuum, press down the pedal.
 - When you lift off your foot, the regulator locks in that position.

4.15.3 Foot regulator set, Art.No. 443.0770.0, with the ATMOS Record 55 DDS Lipo

- Foot regulator for adjusting the quantity of the infiltration solution.
 - Connect the foot regulator to the socket on the left side of the ATMOS 2001 TI.

4.15.4 Mobility of the ATMOS Record 55 DDS

- Loosen the brakes of the forward castors.
- Hoses and cables must be secured on the back before the unit is moved.
- Stand behind the ATMOS Record 55 DDS and push it with one or both hands on the level of the display and operating panel.

5.1 General information on cleaning and disinfection

- For disinfection, you may use all surface and instrument disinfectants listed in chapter 5.4 / 5.5.
- ☞ A number of disinfection agents may cause discoloration at the secretion canister etc., however this has no effect upon the parts's function.
- ☞ Always observe the concentration specifications and instructions by the respective manufacturer !

5.2 Reprocessing of hoses and secretion canister

- ☞ Before using the device on a new patient be sure to clean and sterilize the following parts:
- DDS secretion canister including
DDS secretion canister lid,
DDS hose adapter and
DDS secretion canister handle.
 - Unscrew all hose connectors, pull the DDS hose adapter out of the DDS secretion canister lid, open the lid, empty the secretion canister and dispose of the sucked material properly.
 - Take the DDS bacterial filter out of the DDS secretion canister handle and renew it prior to use on a new patient.
 - All other parts, except the bacterial filter, must also be thoroughly rinsed under running water. Using the cleaning agent neodisher AN or neodisher MediClean forte (manufactured by Dr. Weigert, Hamburg) cleaning in an automatic cleaner and disinfecter is also possible.
Thermal disinfection is carried out at 93° C.
 - Autoclave all of the parts referred to above (134 °C, 3 bar, 5 min. 3x fractionated prevacuum).
 - After sterilization, reassemble all parts (see section 4.0 "Operation").

Max. cycles of reprocessing:
DDS secretion canisters, silicone hoses: 60 cycles

5.0 Cleaning



5.3 Cleaning and disinfecting the unit surface

☞ Always disconnect the device from the power line, before cleaning and disinfecting the surface.

- Wipe the surface clean with a cloth soaked in a cleaning solution or disinfectant. Liquids must not enter the device. All of the cleaning solutions and disinfectants listed below can be used.
- ☞ Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.

5.4 Recommended instrument disinfectants

Disinfectant	Ingredients	(in 100 g)	Manufacturer
GIGASEPT FF (concentrate)	succinic acid dialdehyde dimethoxy tetrahydrofurane corrosion protection components non-ionic tensides and odoriphores	11.0 g 3.0 g	Schülke & Mayr, Norderstedt
Sekusept PLUS (concentrate)	glucoprotamine non-ionic tensides dissolvents, complexing agents	25.0 g	Henkel, Düsseldorf
Mucozit-T (concentrate)	bi3 (3-aminophenyl)laurylamine alkyldimethylbenzylammoniumchloride cocospropylendiamine-1,5 guanidinium-acet.	8.0 % 19.0 % 7.0 %	Merz & Co., Frankfurt/Main

5.5 Recommended surface disinfectants

Disinfectant	Ingredients	(in 100 g)	Manufacturer
TERRALIN (Concentrate)	Benzal conium chloride Phenoxypropanole	20 g 35 g	Schülke & Mayr, Norderstedt
QUATOHEX (Concentrate)	Didecy dimethyl ammonium chloride Benzal conium chloride Bi-guanidinium acetate Polymer biguanid Cleaning agents	14 g 10 g 7,5 g 0,5 g	Braun, Melsungen
Incidin Plus (Concentrate)	Glucoprotamin Nonionic tensides Solvents, complexing agents	26,0 g	Henkel, Düsseldorf
Pursept-A (Disinfectant spray or disinfectant cloths)	Ethanol Glyoxal QAV	38,9 g 0,1 g 0,05 g	Merz & Co., Frankfurt/M.

5.6 Recommended cleaning agents

Disinfectant	Ingredients	(in 100 g)	Manufacturer
neodisher MediClean forte (application concentrate)	non-ionic tensides NTA (nitrilotriacetic acid) enzymes, preservative agent	< 5 g 5-15 g	Dr. Weigert, Hamburg
neodisher AN	Phosphate non-ionic tensides enzymes	> 30 g < 5 g	Dr. Weigert, Hamburg

6.0 Maintenance



- Visually inspect the device, hoses, secretion canister and power cord before each use.
- Parts which are damaged must be replaced immediately.
- The unit does not require any further maintenance.
- For hygienic reasons, the DDS-bacterial filter/oversuction stop must be replaced at least once a day !

Maintenance

Before putting the device into operation, visually check unit, secretion canister and power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately!

A regular safety-related inspection is prescribed every 2 years. In the course of the safety-related check we recommend an inspection of the product.

Reprocessing

Handling of the suction device determines to a large extent its reliability and safety. The hygiene measures described in the previous chapters are necessary measures for the protection of patients and users, and to maintain functional reliability.

Repairs

The following may require repairs from the manufacturer or an authorized service partner. Prior to sending in the device, please contact your service partner by phone.

- Liquids have penetrated the device
- Sudden occurrence of unusual noises
- Operational and functional disorders which cannot be resolved by means of the hints described in the chapter "Troubleshooting".

Measures to be taken prior to sending in the device:

If the device has to be sent in for repair after consultation with the manufacturer or an authorized service partner, we ask you to observe the following:

- Please send in the complete device (see scope of delivery).
- Please remove all disposable parts and consumables.
- Thorough cleaning and disinfection
- Airtight packing
- Please enclose a detailed error description.

Warranty

ATMOS cannot guarantee an error-free function nor can ATMOS be held liable for damage to people or goods if

- non-original ATMOS parts are used,
- the information in these operating instructions are disregarded,
- assembly, new installations, modifications, extensions and repairs are done by people who are not authorised by ATMOS.

7.0 Trouble-shooting



The ATMOS Record 55 DDS was subjected to a thorough quality control before shipment. If there is, nevertheless, some malfunction, you possibly might solve this problem yourselves if you observe the following instructions.

Problem	Possible causes	Remedy
● Unit does not start	<ul style="list-style-type: none"> – Loose power plug – No power voltage – Defective fuse 	<ul style="list-style-type: none"> – Check connection to supply socket – Check inbuilding fuse – Replace fuse
● Insufficient performance, vacuumgauge shows high vacuum value	<ul style="list-style-type: none"> – Filter is clogged 	<ul style="list-style-type: none"> – Insert dry and clean filter
● Insufficient performance, vacuumgauge shows low vacuum value	<ul style="list-style-type: none"> – Leakages within the hose system or in the secretion canister lid – Secretion or blood has been sucked in and valve plates of the pump are contaminated – Bellows is worn out 	<ul style="list-style-type: none"> – Check secretion canister lid and hose system, check gaskets on secretion canister lid – Unit has to be repaired by our service staff – Replace bellows

8.0 Spare parts and accessories

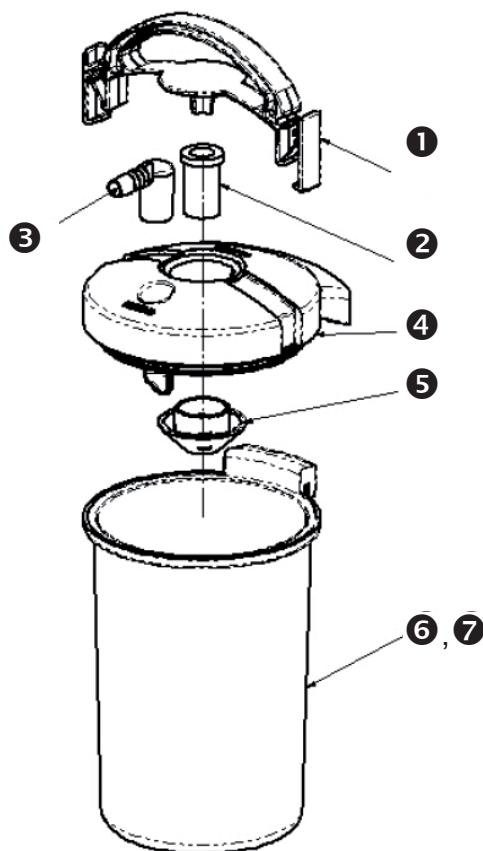


Fig. 22.

8.1 Spare parts

Description	REF
① DDS-canister handle.....	340.0055.0
② DDS-bacterial filter/oversuction stop, hydrophobic, disposable part, 10 pcs.	340.0054.0
③ DDS-hose adaptor set, Ø 6 + 10 mm	340.0057.0
④ DDS-canister lid with gaskets	340.0053.0
⑤ DDS-splash protection	340.0056.0
⑥ DDS-secretion canister, APEC, 3.0 l.....	340.0051.0
⑦ DDS-secretion canister, APEC, 5.0 l.....	340.0052.0

Spare parts (without illustrations)

DDS-switchover docking station for 2 canisters 340.0080.0	
Fuse 230 V T 0.63 A/H	008.0634.0
Fuse 115 V T 1.25 A/H.....	008.0720.0
Mains cable	008.0629.0
Suction hose, silicone, Ø 10 mm, 2 m.....	000.0243.0
Suction hose, silicone, Ø 6 mm, 2 m.....	000.0361.0
Suction hose, silicone, Ø 6 mm, 1.30 m.....	000.0013.0
Suction hose, disposable, Ø 6 mm, 1,30 m	006.0057.0
Suction hose, disposable, Ø 6 mm, 2.10 m.....	006.0059.0
Bellows, silicone rubber.....	000.0739.0
Operating instructions.....	444.0910.1

8.2 Accessories

8.2.2 Facilities to simplify the handling

Description	REF
Foot regulator set	443.0770.0
Foot switch	443.0755.0
Tray with rail adaptor	443.0790.0
Hose holder on canister.....	340.0066.0
Catheter quiver for flex. catheters	444.0140.0
Catheter quiver with holder for rail system (for catheter storing)	443.0780.0
Quiver holder, small; incl. standard rail holder.....	444.0145.0
Hose holder, for attaching to standard rail (white plastic).....	444.0450.0

8.2.3 Accessories for General Surgery, Anaesthesia, Intensive Care

Yankauer OP suction cannula, length = 270 mm	401.0610.0
Yankauer OP suction cannula, length = 250 mm (disposable part, sterile), 50 pcs.....	401.0611.0
Poole OP suction cannula	401.0608.0
Poole OP suction cannula, length = 280 mm (disposable part, sterile), 50 pcs.....	401.0609.0
Unoplast suction catheters "Optimal", straight, size: Charrière 12, central opening, 2 small lateral openings, length: 50 cm, (disposable part, sterile), 100 pcs.....	000.0294.0
Unoplast suction catheters "Optimal", straight, size: Charrière 14, central opening, 2 small lateral openings, length: 50 cm, (disposable part, sterile), 100 pcs.....	000.0295.0
Unoplast suction catheters "Optimal", straight, size: Charrière 16, central opening, 2 small lateral openings, length: 50 cm, (disposable part, sterile), 100 pcs.....	000.0296.0
Hose connector (finger tip), sterile.....	000.0347.0
Hose connector (finger tip), sterile, 100 pcs	000.0347.1

8.2.4 Gynaecology

Description	REF
Suction curette, with auxiliary air vent, external Ø 6 mm.....	401.0529.0
Suction curette, with auxiliary air vent, external Ø 8 mm.....	401.0530.0
Suction curette, with auxiliary air vent, external Ø 10 mm.....	401.0531.0
Suction curette, with auxiliary air vent, external Ø 12 mm.....	401.0532.0
Suction curette, without auxiliary air vent, external Ø 6 mm.....	401.0539.0
Suction curette, without auxiliary air vent, external Ø 8 mm.....	401.0541.0
Suction curette, without auxiliary air vent, external Ø 10 mm.....	401.0543.0
Suction curette, without auxiliary air vent, external Ø 12 mm.....	401.0545.0
Suction curette, without auxiliary air vent, external Ø 14 mm.....	401.0547.0
Suction curette, for test taking, Ø 3 mm	401.0554.0
Suction curette, for test taking, Ø 4.5 mm	401.0528.0
Swivel coupling (connecting adaptor for curettes mentioned above).....	401.0553.0
Tissue collector, 300 ml (disposable part)	340. 0061.0
Adaptor for tissue collector	340. 0062.0
Collector sieve (for analysis with abortus curettages), disposable part.....	401.0555.0

8.2.5 Cannulae, Cardiovascular/Thorax Surgery

Cooley OP suction cannula, length = 350 mm#	401.0612.0
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8.2.6 Cosmetic/Plastic Surgery

Basic Set (cannulae No. 6 - No. 12 / standard handle)	401.0620.0
Fine Set (cannulae No. 1 - No. 5 / dosage handle)"	401.0615.0

8.2.7 ENT Cannulae

Frazier ENT suction cannula 8 CH#	401.0606.0
Frazier ENT suction cannula 10 CH#	401.0606.0

#with suction interruption opening

9.0 Technical Specifications



9.1 Technical Specifications ATMOS Record 55 DDS

Air flow rate of pump	55 ± 3 l/min.
Max. vacuum at sea level	-98 kPa (-980 mbar or -735 mmHg)*
Vacuum readout	-1...0 bar (± 25 mbar)
Additional air regulation	mechanical regulating valve
Secretion canister	APEC canister set 2 x 3 l (REF 444.0901.0) resp. 2 x 5 l (REF 444.0902.0)
Suction hose	Ø 6mm, 2 m length; Ø 10 mm, 2 m length
Voltage	230 V~, 50/60 Hz
Current input (max.)	approx. 0.45 A for 230 V~
Power consumption	approx. 100 W
Power cable	5 m
Operating time	>8 h continuous operation (depending on ambient conditions)
Fuse	T 630 mA/H for 230 V~
Protective earth conductor resistance	< 0.1 Ω
Earth leakage current	N.C. < 0.5 mA
Enclosure leakage current	N.C. < 0.1 mA
Patient leakage current	—
Heat emission	100 J/s
Noise level	46 dB (A) @ 1m (acc. to ISO 7779)
Ambient conditions	
Transport/storage	-30...+50°C; 5...90 % humidity, non-condensing air pressure 700...1060 hPa
Operation	+10...+32°C; 20...80 % humidity, non-condensing air pressure 700...1060 hPa
Dimensions HxBxT	940 x 500 x 390 mm, without secretion canisters
Weight	24 kg, without secretion canisters
Protection class (EN 60601-1)	I
Degree of protection	Typ BF
Protection category	IPX 1
Classification acc. to Annex IX EEC directions 93/42/EEC	IIa
CE marking	CE 0124
Rules applied	EN 60601-1:1990 + A1: 1993 + A2: 1995 EN ISO 10079-1: 11/1996 EN 60601-1-2: 1993 (EMV / EMC), EN 30993: 1994
UMDNS-Code	17-217 17-103
GMDN-Code	36777
Reference-No.	444.0910.0

Canadian Classification	
Device Group	General & Plastic Surgery
PNC	79QBU
Risk Class	2
Description	Aspirator, Surgical

* 1 bar ≈ 750,06 mm Hg ≈ 1000 hPa / depends on daily atmospheric pressure



9.2 Technical Specifications ATMOS Record 55 DDS Lipo

- As with the ATMOS Record 55 DDS (Chapter 9.1) but REF 444.0920.0.
- Technical Specifications for the tumescence infiltration pump ATMOS S 2001 TI are contained in the respective operating instructions.

10.0 Disposal



- The ATMOS Record 55 DDS does not contain any hazardous goods.
- The material of the housing can be recycled completely.
- The component parts of the ATMOS Record 55 DDS must be disposed off correctly and the materials are to be separated carefully.

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

11.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS Record 55 DDS is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS Record 55 DDS should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ATMOS Record 55 DDS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ATMOS Record 55 DDS is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Inapplicable	



The device may not be used directly next to other devices or piled up with other devices.
If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

11.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS Record 55 DDS is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS Record 55 DDS should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains Inapplicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 1 kV Common	± 2 kV Differential ± 1 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	<p>< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle</p> <p>40 % U_T (60% Dip of the U_T) for 5 Cycles</p> <p>70% U_T (30 % Dip of the U_T) for 25 Cycles</p> <p>< 5 % U_T (>95 % Dip of the U_T) for 5 s</p>	<p>< 5 % U_T (> 95 % Einbruch der U_T) für 0,5 Periode</p> <p>40 % U_T (60% Einbruch der U_T) für 5 Perioden</p> <p>70% U_T (30 % Einbruch der U_T) für 25 Perioden</p> <p>< 5 % U_T (>95 % Einbruch der U_T) für 5 s</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS Record 55 DDS demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS Record 55 DDS from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

1.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS Record 55 DDS is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS Record 55 DDS should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V _{eff}	Portable and mobile communications equipment should be separated from the ATMOS Record 55 DDS incl. the cables by no less than the distances calculated/listed below.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Recommended distances:</p> $d = (3,5 / V1) * \sqrt{P}$ $d = (3,5 / E1) * \sqrt{P} \quad 80-800 \text{ MHz}$ $d = (7 / E1) * \sqrt{P} \quad 0,8-2,5 \text{ GHz}$ <p>where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol.</p> 

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines don't like to be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

- a The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS Record 55 DDS is used exceeds the above compliance level, the ATMOS Record 55 DDS is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.
- b Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

11.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS Record 55 DDS

The ATMOS Record 55 DDS is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS Record 55 DDS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS Record 55 DDS as recommended below, according to the maximum output power of the communications equipment.

Nominal output of the transmitter W	Separation distance, depending on transmit-frequency m		
	150 kHz bis 80 MHz $d = [3,5 / 3] \sqrt{P}$	80 MHz bis 800 MHz $d = [3,5 / 3] \sqrt{P}$	800 MHz bis 2,5 GHz $d = [7,0 / 3] \sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,2	1,2	2,4
10	3,69	3,69	7,38
100	11,66	11,66	23,32

For transmitters for which the maximum nominal output isn't indicated in the above table, the recommended separation distance d in meters (m) can be determined using the equation belonging to the respective column whereas P is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer's specification.

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines are not applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved. Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coincidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that

case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compensation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

is limited to damage which is regarded as typical for that case. This also applies in the case of our culpable infringement of substantial contractual duties. The indispensable conditions of German Liability Law remain unaffected thereby.

- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

- a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;
- b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.
- c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;
- d. We accept no responsibility for damage defects caused by
 - operational wear and tear;
 - incorrect installation or incorrect or insufficient maintenance;
 - incorrect operation of the product (in contradiction to the operating instructions delivered with the product); - improper use or operating faults; - inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation; - using accessories and/or replacement parts which are not explicitly approved;
 - incorrect assembly and/or initial operation by the client or third parties; - the client's negligence in handling the product; - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.
 - accidents, acts of God, especially lightning, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods represents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income from such use is balanced against the client's arrears, after deducting appropriate utilisation costs. The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby. We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law. Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, September 2008

**ATMOS MedizinTechnik GmbH & Co. KG
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